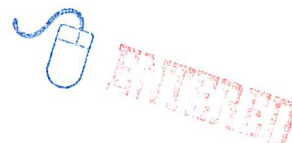




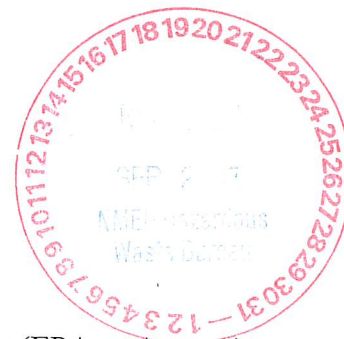
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
AIR AND RADIATION

Sept. 12, 2003

Dr. Inés Triay, Manager
U.S. Department of Energy
Carlsbad Field Office
4021 National Parks Highway
Carlsbad, NM 88220



Dear Dr. Triay:

From July 29-30, 2003, the U.S. Environmental Protection Agency (EPA or Agency) conducted a follow-up audit of the Hanford Site's Quality Assurance (QA) Program for the Waste Isolation Pilot Plant (WIPP). The purpose of EPA's follow-up audit was to verify correction of a deficiency identified during a previous audit. The EPA determined during the follow-up audit that Hanford had corrected the deficiency.

During a previous audit, conducted in June 2003, EPA found that Hanford's management had not provided its QA Organization with sufficient authority nor sufficient independence from cost and schedule considerations to properly verify that waste characterization activities have been correctly performed. The EPA believed that the deficiency appeared sometime after January 1, 2003. We conveyed the results of the June inspection in a letter dated July 21, 2003 (Docket II-A1-46). In the letter, we required that Transuranic (TRU) wastes characterized after January 1, 2003, shall not be disposed at the WIPP until the EPA verified corrective actions. TRU waste that was characterized before that date required Department of Energy (DOE) QA approval prior to disposal.

During the follow-up audit conducted in July 2003, the EPA found that Hanford's management increased the QA Organization's authority and organizational freedom. In addition, further EPA analysis indicated that the deficiency emerged after February 1, 2003. Therefore, EPA has revised its restrictions on Hanford's waste disposal. Transuranic (TRU) waste that was characterized before February 1, 2003, may be disposed at the WIPP without additional approvals by the EPA. TRU waste characterized during the period between February 1, 2003,

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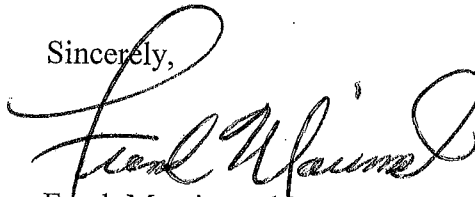
and July 31, 2003, using EPA-approved waste characterization (WC) processes may be shipped to the WIPP only after EPA is notified and approves shipment. Upon notification, the EPA will verify that Hanford's QA Organization has provided adequate oversight of WC for particular containers comprising each waste shipment. Waste characterized beginning August 1, 2003, may be disposed at WIPP without additional approvals by EPA.

The EPA identified two concerns during the recent inspection. First, the additional resources assigned to the Hanford QA program, while adequate at this time, may not be sufficient to keep pace with the resource needs for the increased workload anticipated over the next year. Second, EPA is also concerned that some sections of the current Hanford QA Plan may not be in clear conformance with EPA requirements. EPA will further evaluate these two concerns during another follow-up audit planned for September 2003.

I am also concerned that the *Organization* deficiency has previously occurred, several times, in other WIPP organizations. I expect that this will be an area of emphasis for EPA in upcoming QA audits. I ask that DOE also seek to identify effective measures to preclude further recurrence. For example, DOE can expedite approval of QAPD changes that provide a clearer establishment of the *Organization* requirements of the Nuclear Quality Assurance standards.

This report will be made available to the public through the Agency's public docket. Please contact Betsy Forinash at (202) 564-9310 or Mike Eagle at (202) 564-9376 if you have questions regarding the report.

Sincerely,



Frank Marcinowski

Director, Radiation Protection Division

Enclosure

cc: Ava Holland (CBFO) (w/enclosure)
Matthew Silva (EEG) (w/enclosure)
✓ Steve Zappe (NMED) (w/enclosure)

**DOCKET NO: A-98-49
II-A1-51**

**EPA FOLLOWUP AUDIT OF THE DOE HANFORD SITE
QUALITY ASSURANCE PROGRAM
FOR THE WASTE ISOLATION PILOT PLANT**

July 29-30, 2003

**U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Radiation and Indoor Air
Center for Federal Regulations
1200 Pennsylvania Ave., NW
Washington, D.C. 20460**

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1.0 EXECUTIVE SUMMARY

From July 29-30, 2003, the U.S. Environmental Protection Agency (EPA or Agency) conducted a follow-up audit of the Hanford Site's Quality Assurance (QA) Program for the Waste Isolation Pilot Plant (WIPP). The purpose of EPA's follow-up audit was to verify correction of a deficiency identified during a previous audit. The EPA determined during the follow-up audit that Hanford had corrected the deficiency.

During a previous audit, conducted in June 2003, EPA found that Hanford's management had not provided its QA Organization with sufficient authority, nor sufficient independence from cost and schedule considerations to properly verify that waste characterization activities have been correctly performed. EPA believed that the deficiency appeared sometime after January 1, 2003. At that time, EPA concluded that Hanford wastes characterized after January 1, 2003, shall not be disposed of at the WIPP.

During the follow-up audit conducted in July 2003, the EPA found that Hanford's management increased the QA Organization's authority and organizational freedom. In addition, further EPA analysis indicated that the deficiency emerged after February 1, 2003. Therefore, EPA has revised its restrictions on Hanford's waste disposal. Transuranic (TRU) waste that was characterized before February 1, 2003, may be disposed at the WIPP without additional approvals by the EPA. TRU waste characterized during the period between February 1, 2003, and July 31, 2003, using EPA-approved waste characterization (WC) processes may be shipped to the WIPP only after EPA is notified and approves shipment. Upon notification, the EPA will verify that Hanford's QA Organization has provided adequate oversight of WC for the particular containers comprising each waste shipment. Waste characterized beginning August 1, 2003, may be disposed at WIPP without additional approvals by EPA.

The EPA is also concerned that the *Organization* deficiency has previously occurred, several times, in other WIPP organizations. EPA asks that DOE take more effective proactive steps, prior to the EPA audits, to preclude further recurrence. For example, DOE can expedite approval of changes to the Quality Assurance Program Description (QAPD) that provide a clearer establishment of the *Organization* requirements of the Nuclear Quality Assurance standards.

The EPA also found two other concerns. The EPA is concerned that the additional resources assigned to the Hanford QA program, while adequate at this time, may not be sufficient to keep pace with the resource needs for the increased workload anticipated over the next year. EPA is also concerned that some sections of the current Hanford QA Plan may not be in clear conformance with EPA requirements. EPA will further evaluate these two concerns during another follow-up audit planned for September 2003.

This report will be made available to the public through the Agency's public docket.

2.0 BACKGROUND

2.1 Regulatory Background

In January 2000, EPA initially determined the Hanford Site's compliance with U.S. Environmental Protection Agency (EPA or Agency) requirements for Quality Assurance (QA) programs. This was done by the EPA in accordance with 40 CFR §194.8(a)(1) &(2). The EPA requires the transuranic (TRU) waste generator sites, such as the Hanford Site, to implement the following Nuclear Quality Assurance (NQA) standards: 1) ASME NQA-1-1989 edition; 2) ASME NQA-2a-1990 Addenda, Part 2.7, to ASME NQA-2-1989 edition; and 3) ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c) and Section 17.1). In accordance with 40 CFR §194.8(a)(3), EPA provided a written initial determination that the Hanford QA Program complied with the NQA standards.

Subsequent to the initial determination of compliance in January 2000, the EPA has conducted five additional audits, in accordance with §194.8(a)(4), to determine continued compliance. This report documents EPA's fifth audit to determine continued compliance.

The EPA periodically audits Department of Energy's (DOE) Carlsbad Field Office (CBFO) and has found that CBFO's QA Organization can properly audit the generator sites' QA Programs. During an EPA audit, the EPA assumes all responsibilities associated with assessing a QA Program. During an EPA inspection, the Agency performs some oversight of CBFO's checks of a generator site's QA program. Further, EPA performs some independent assessment, or audit-type, activities during the course of inspecting a CBFO audit. The table below presents a summary of EPA inspection and audit activities conducted of the Hanford's QA Program to date.

Summary of EPA Inspections and Audit Activities at the Hanford Site		
Activity	Date	Purpose
Inspection	January 24-28, 2000	Inspection and independent assessment of initial CBFO Certification Audit A-00-05 of QA program for conformance with 40 CFR 194.8(a)
Inspection	January 16, 2001	Inspection and independent assessment of CBFO Surveillance S-01-04 for maintenance of QA program for conformance with 40 CFR 194.8(a)
Inspection	June 12-15, 2001	Inspection of CBFO Audit A-01-03 and A-01-16 of QA

		program maintenance.
Inspection	June 25-27, 2002	Inspection of CBFO Audit A-02-23 of QA program maintenance.
Inspection	June 24-26, 2003	Inspection of CBFO Audit A-03-14 of QA program maintenance.
Audit	July 29-31, 2003	Followup audit to verify corrective actions resulting from the June 2003 EPA Inspection

2.2 Hanford Site Background

Hanford, located along the Columbia River near Richland, Washington, is a 560-square-mile area managed by the DOE. Hanford was established in secrecy during World War II to produce plutonium for the United States' nuclear weapons program. Peak production years were reached in the 1960s when eight nuclear reactors were operating at Hanford. All weapons material production was halted in the late 1980s. Hanford is now engaged in the world's largest environmental cleanup project. TRU wastes generated at Hanford during the production years and during environmental cleanup are destined for disposal at the Waste Isolation Pilot Plant (WIPP), the geologic repository for the disposal of the nation's TRU wastes. Hanford serves as an interim storage facility for defense-generated TRU-contaminated waste. Hanford is also responsible for the waste characterization (WC) of TRU-contaminated waste that will be disposed at the WIPP. In addition, Hanford is responsible for executing a QA Program to oversee its TRU W.C. activities.

3.0 PURPOSE AND SCOPE

Section 194.22(a)(1) requires that DOE establish and implement the requirements of: 1) ASME NQA-1-1989 edition; 2) ASME NQA-2a-1990 Addenda, Part 2.7, to ASME NQA-2-1989 edition; and 3) ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c) and Section 17.1). The purpose of this EPA audit was to confirm the continued compliance of Hanford's QA Program with the above requirements.

Section 194.22(a)(2) requires that DOE properly execute a QA Program for all items and activities that are important to the containment of TRU-waste at the WIPP. The scope of this EPA audit was Hanford's QA Program's oversight of items and activities that are important to the containment of TRU waste at the WIPP. Currently, Hanford characterizes contact-handled (CH) TRU waste that is destined for disposal at the WIPP, an activity listed under 194.22(a)(2)(i).

Therefore, the scope of EPA audits and inspections are limited to the QA Program's oversight of the WC activities. Section 194.22(a)(2) reads as follows:

- (2) Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been established and executed for:
 - (i) Waste characterization activities and assumptions;
 - (ii) Environmental monitoring, monitoring of the performance of the disposal system, and sampling and analysis activities;
 - (iii) Field measurements of geologic factors, ground water, meteorologic, and topographic characteristics;
 - (iv) Computations, computer codes, models and methods used to demonstrate compliance with the disposal regulations in accordance with the provisions of this part;
 - (v) Procedures for implementation of expert judgment elicitation used to support applications for certification or re-certification of compliance;
 - (vi) Design of the disposal system and actions taken to ensure compliance with design specifications;
 - (vii) The collection of data and information used to support compliance application(s); and
 - (viii) Other systems, structures, components, and activities important to the containment of waste in the disposal system.

The EPA further limited the scope of this audit to the verification of corrective actions as a result of the finding of non-conformance resulting from the June 2003 EPA inspection (Docket II-A1-46). The finding of non-conformance was as follows:

40 CFR Part 194.22 requires DOE to execute a QA program for items and activities that are important to the containment of TRU waste within the WIPP, including the TRU WC activities at the Hanford Site. Hanford's QA program must be in accordance with the Nuclear Quality Assurance (NQA) standards developed by The American Society of Mechanical Engineers. The *Organization* element of the NQA standards requires that "...organizations responsible for...verifying that activities affecting quality have been correctly performed...shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations." However, personnel interviews during the audit indicated that Hanford's QA Organization did not have sufficient independence from cost and schedule considerations. In addition, resources for the QA Organization appeared insufficient for a growing rate of waste characterization activities.

4.0 DEFINITIONS

Finding: A determination that a specific item or activity does not meet a requirement under applicable elements of the NQA standards. A finding requires a response.

Concern: A judgment that a finding may occur in the future, and depending on the magnitude of the issue, may or may not require a response.

Quality: The reliability or worth of a specific item or activity that is important to the containment of TRU waste at the WIPP. *Quality Achievement* is the responsibility of operational groups that directly produce such an item or perform such an activity. *Quality Verification* is the responsibility of QA Organizations that do not produce such items or perform such activities. A failure to achieve quality is not the responsibility of the QA organization that verifies quality achievement. Further, demonstrations that quality has been achieved are the responsibility of operational groups that are responsible for *Quality Achievement*.

5.0 INSPECTION TEAM AND PARTICIPANTS

The EPA inspection team consisted of the following personnel:

<u>Team Member</u>	<u>Position</u>	<u>Affiliation</u>
Mike Eagle	Lead Auditor	EPA's Office of Radiation and Indoor Air
Bill Vocke	Auditor	ICF Consulting

Ms. Amy Arceo, Auditor from the CBFO Technical Assistance Contractor (CTAC), observed the EPA audit for CBFO's QA Organization.

6.0 PERFORMANCE OF THE AUDIT

The EPA auditors conducted interviews to verify that Hanford management has taken corrective action to address the *Organization* finding identified during the June 2003 inspection. The EPA conducted extensive interviews of the following Hanford personnel:

1. Dana Farwick, Hanford QA Management.
2. Jim Maupin, Hanford's Acting Site Quality Assurance Officer (SQAQO).
3. Stewart Huggins, Hanford QA Engineer.

6.1 General Results and Restrictions

Based on interviews of Hanford personnel, EPA finds that the Hanford QA Organization has additional access to senior management at a level where appropriate action can be effected. Hanford's senior management appears to provide the QA Organization with additional authority, organizational freedom and resources and to resolve the *Organization* finding. (See section 7.1 of this report for a more detailed description of resolution of the EPA finding.)

EPA also examined Hanford data packages to support interview information. The interviews and data packages indicated that the breakdown in *Organization* occurred after February 1, 2003.

The EPA's restrictions on waste disposal are as follows:

TRU wastes that were characterized before February 1, 2003, shall not require EPA approval on individual shipments prior to shipment. Transuranic (TRU) waste that was characterized before February 1, 2003, may be disposed at the WIPP without additional approvals by the EPA. TRU waste characterized during the period between February 1, 2003, and July 31, 2003, using EPA-approved waste characterization (WC) processes may be shipped to the WIPP only after EPA is notified and approves shipment. Upon notification, the EPA will verify that Hanford's QA Organization has provided adequate oversight of WC for the particular containers comprising each waste shipment. Waste characterized beginning August 1, 2003, may be disposed at WIPP without additional approvals by EPA.

6.2 Findings and Concerns

The EPA verified resolution of one finding and issued three new concerns.

6.2.1 June 2003 Finding Regarding *Organization*

The June 2003 Finding is as follows:

40 CFR Part 194.22 requires DOE to execute a QA program for items and activities that are important to the containment of transuranic waste within the WIPP, including the TRU WC activities at the Hanford Site. Hanford's QA program must be in accordance with the Nuclear Quality Assurance (NQA) standards developed by The American Society of Mechanical Engineers. The *Organization* element of the NQA standards requires that "*...organizations responsible for...verifying that activities affecting quality have been correctly performed...shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.*" However, personnel interviews during the audit indicated that Hanford's QA Organization did not have sufficient independence from cost and schedule considerations. In addition, resources for the QA Organization appeared insufficient for a growing rate of waste characterization activities.

During the June inspection, the EPA found that Hanford's QA resources were not keeping pace with increasing activities in characterizing CH TRU. The quantity of field inspections performed by Hanford QA staff was not sufficient to properly verify the quality of WC activities. The QA staff was working overtime just to keep up with reviews of QA records. The EPA found that organizational changes had significantly eroded too the authority of the QA Organization. Access to upper management had decreased since a reorganization that occurred around Fall 2002, and weekly meetings between the SQAQO and senior management were no longer taking place. The SQAQO did not seem to have the same level of authority as seen during the previous EPA inspection. The SQAQO was no longer a direct employee of Fluor Hanford. Operational groups were challenging the independence of the QA Organization. The Plutonium Finishing Plant operational groups were exerting pressure on the QA Organization through new management that was insufficiently aware of EPA requirements. The QA Organization generally resisted these pressures successfully in most instances.

During this audit, EPA verified that Hanford has conducted appropriate corrective actions to resolve the Finding. Hanford management has assigned two additional FTEs to support the QA Program and efforts are underway to make an additional two FTEs available. In addition, the Hanford QA Program provided evidence that quarterly reviews of data packages are ongoing and provide assurance that adequate QA reviews of data packages are occurring. Therefore, the EPA considers the June Finding closed with the following revised restrictions on waste shipments from Hanford to the WIPP:

1. TRU waste that was characterized before February 1, 2003, may be disposed at the WIPP without additional approvals by the EPA.
2. TRU waste characterized during the period between February 1, 2003, and July 31, 2003, using EPA-approved WC processes may be shipped to the WIPP only after EPA is notified and approves shipment. Upon notification, the EPA will verify that Hanford's QA Organization has provided adequate oversight of WC for the particular containers comprising each waste shipment.
3. Wastes characterized after August 1, 2003, may be shipped to WIPP without additional approval of the EPA.

6.2.2 Concern Number 1

The EPA is also concerned that the *Organization* deficiency has previously occurred, several times, in other WIPP organizations. EPA asks that DOE take more effective proactive steps, prior to the EPA audits, to preclude further recurrence. For example, DOE can expedite approval of changes to the Quality Assurance Program Description (QAPD) that provide a clearer establishment of the *Organization* requirements of the Nuclear Quality Assurance standards.

6.2.3 Concern Number 2

EPA is concerned that the current Hanford QA Plan may not be in conformance with the NQA-1 standard (1989 edition). EPA did not evaluate this issue because it was outside the scope of the

audit. However, EPA notes that 40 CFR 194.22 requires that NQA-1 (1989 edition) be established in QA Plans for items and activities that are important to the containment of TRU waste in the WIPP. The Hanford site performs WC activities that are important to the containment of TRU waste. Therefore, the Hanford QA plan must establish the applicable NQA-1 elements for the characterization of TRU waste. However, the Hanford QA Plan may not have properly established organizational responsibilities in accordance with element 1, *Organization*, of NQA-1. EPA will evaluate this concern during a follow up audit in September 2003 to verify the proper establishment of applicable NQA requirements in the Hanford QA Plan.

6.2.4 Concern Number 3

EPA is concerned that the additional resources assigned to the QA program, while adequate at this time, may not be sufficient to keep pace with the resource needs for the increased workload anticipated over the next year. In response to the EPA finding from the June 2003 inspection, Hanford management assigned two additional FTEs to the QA program, raising the staff resources to six. Hanford is in the process of issuing a request for proposals to provide two additional FTEs of support to the QA program. This additional staffing has corrected the situation that was found during the June 2003 inspection.

EPA is concerned that the planned acceleration of shipments to WIPP from the current 6 to 8 per month up to 16 per month, may overwhelm the QA resources and create a repeat of the condition found during the June inspection. The June Finding was issued because the staffing level (four FTEs) was inadequate to meet the demands to process enough data packages for the six to eight shipments each month. The resulting backlog of data packages fostered an environment where cost and schedule concerns were interfering with the ability of the QA Program to perform its work. The additional FTEs have alleviated the situation at this time. However, if the shipment schedule is accelerated to 16 per month, the increased workload demand on the QA staff will be equivalent to that which resulted in the Finding.

EPA will evaluate this concern during a follow up audit in September 2003.

7.0 References

Flour Daniel. "TRU Waste Project Quality Assurance Report to Management" (Document FH-0300834) File: TRU-SPO-10.1-0311200349576. January 31, 2003.

Flour Daniel. Batch Data Report for Sampling and Analytical Batch Number 030127 for Waste Stream NPFPD (Document WSCF-030127V1). File: TRU-WSCF-11.10-0616200330743. April 23, 2003.

Flour Daniel. Batch Data Report for Sampling and Analytical Batch Number 030127 for Waste Stream NPFPD (Document WSCF-030127V1). File: TRU-WSCF-11.3-0213200340267. January 27, 2003.

Flour Daniel. "Quarterly Report of Generation Level Data Validation April through June 2003 for Container RHZ-213-A19470 Waste Stream Lot Number NPFPD" File: TRU-WRP-11.10-0724200346960.

Flour Daniel. "Quarterly Report of Generation Level Data Validation January through March 2003 for Container RHZ-213-A22417 Waste Stream Lot Number NPFPD" File: TRU-WRP-11.10-0724200346960.